IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC., Plaintiff, v. IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC AND ALCON INC., Defendants.	)	C. A. No.: 21-1317-GBW-SRF **JURY TRIAL DEMANDED** [redacted] **Public Version Filed on: November 14, 2023**

CONCISE STATEMENT OF ADDITIONAL FACTS IN SUPPORT OF SIGHT SCIENCES, INC.'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT NO. 3 OF INVALIDITY FOR INDEFINITENESS

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1. A POSA would understand with reasonable certainty the scope of the Asserted Claims that contain one of the limitations that Defendants collectively refer to as the "Block Limitation" (*see* D.I. 301, ¶2). (Ex. 90 (Downs Reb.) ¶1118; Ex. 96 (Downs CC Decl.) ¶¶20-26.)

2. Sight's position on or interpretation of the Block Limitations has been consistent. The Court has construed the Block Limitation to mean: "the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels," and Sight and Sight's technical expert, Dr. Downs, have consistently applied this definition, which explicitly recites fluid outflow from the trabecular meshwork. (*See, e.g.*, D.I. 59 (2d Am. Complaint) ¶¶51-53, 56 (alleging that fluid outflow through the trabecular meshwork into Schlemm's canal occurs through the accused Hydrus's fenestrations and is not significantly blocked by the device); Ex. 97 (Downs Op.) ¶¶87-91, 95-96; Ex. 90 (Downs Reb.) ¶¶168, 171; Ex. 93 (Downs 9/28 Tr.) 32:5-13.)

3. A POSA would understand that the Asserted Patents provide numerous examples of supports that satisfy the Block Limitation, including, *e.g.*, those pictured Figures 5B-12H. (*See e.g.*, '443, Figs. 5B-12H; Ex. 96 (Downs CC Decl.) ¶¶23-24 ("The Asserted Patents also helpfully provide numerous examples of supports that do, or do not, significantly block the . . . transmural flow of aqueous humor."); Ex. 90 (Downs Reb.) ¶¶1109-1115; Ex. 93 (Downs 9/28 Tr.) 130:14-132:4.)

4. The Asserted Patents also provide instructive examples of supports that would not satisfy the Block Limitation, including, *e.g.*, solid-walled tubular stents inserted into Schlemm's canal. (Ex. 96 (Downs CC Decl.) ¶¶23-24; Ex. 90 (Downs Reb.) ¶1109; Ex. 93 (Downs 9/28 Tr.) 37:11-21, 85:16-87:19, 95:6-16.)

5. The Asserted Patents also describe a "common characteristic" of devices (*i.e.*, minimal contact with the walls of Schlemm's canal), allowing a POSA to distinguish with

reasonable certainty between supports that substantially interfere and those that do not. (*See* '443, 10:61-65 ("A common characteristic . . . is that [supports] need not have continuous or extensive contact with a wall of Schlemm's canal. Indeed, many of the described devices and structures have minimal tangential, periodic, or sporadic contact with the wall."), 11:30-38; Ex. 96 (Downs CC Decl.) ¶24; Ex. 90 (Downs Reb.) ¶¶1109-1110, 1114.)

6. This Court previously rejected Defendants' argument that the Block Limitations are relative and subjective terms that rendered them indefinite, stating: "[a] person of ordinary skill reading this disclosure would understand the relationship between the support's contact with the canal walls and the amount of fluid outflow and would appreciate that the support can be designed in a manner to minimize the impact. A person of ordinary skill would be able to distinguish between supports that substantially interfere and those that do not based on a review of the Asserted Patents' written description." (D.I. 134 at 22-23 (internal citations omitted).)

7. The Court's construction of Block Limitation terms (*i.e.*, "the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels") does not command any specific analysis or testing that must be performed by a POSA to determine or confirm whether a device satisfies this limitation. (D.I. 287 at 1; D.I. 134 at 21-25; D.I. 273 at 6-7.)

8. A POSA could conduct a flow analysis—using analytical or computational modeling, cadaver eye perfusion testing, fluorescence studies, and/or the skill, knowledge, and experience possessed by a POSA—in view of the teachings of the Asserted Patents, to conclude with reasonable certainty that a support would not significantly block flow when implanted *in vivo*. (Ex. 93 (Downs 9/28 Tr.) 45:5-19, 64:10-65:7, 73:9-20, 77:19-78:14, 86:2-19, 95:6-16, 98:10-100:11, 108:18-109:12, 111:18-114:17, 116:15-117:5, 130:14-132:4; Ex. 96 (Downs CC Decl.) ¶25; Ex.

90 (Downs Reb.) ¶¶168-171, 1068-1069, 1072-1078, 1082-1087, 1099-1100, 1118; *see also* Ex. 100 (Downs Reply) ¶¶56, 63.)

9. A POSA would understand the method(s) by which a device could or should be analyzed or tested to confirm whether it would or would not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels based on the design of the device. (Ex. 93 (Downs 9/28 Tr.) 73:9-74:11, 77:19-78:14, 95:6-16, 103:5-15, 112:22-114:2, 116:15-117:5.)

10. Analytical or computational modeling were known methods by which a POSA could determine with reasonable certainty whether a device of any design would satisfy the Block Limitation via the application of well-understood principles of fluid mechanics. (*See, e.g.*, Ex. 90 (Downs Reb.) ¶¶168-171, 173; Ex. 93 (Downs 9/28 Tr.) 64:10-65:25, 69:3-71:4, 73:9-74:11, 84:10-85:3, 98:10-99:2.)

11. Both sides have acknowledged that perfusion testing was a known method that a POSA could use to confirm whether a device did or did not satisfy the Block Limitation. (Ex. 93 (Downs 9/28 Tr.) 45:5-19, 108:18-109:12, 112:22-114:17, 158:4-13; Ex. 96 (Downs CC Decl.) ¶25; Ex. 101 (Tanna 12/15 Tr.) 161:22-162:8, 163:13-21.) For devices that included a shunt or bypass in addition to the inventive support structure with minimal contact with the walls of Schlemm's canal used to restore and promote natural aqueous outflow through the natural outflow pathways, a POSA would have understood that fluorescent dyes could be used in such perfusion testing to confirm that the device facilitated and did not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels. (Ex. 93 (Downs 9/28 Tr.) 113:12-114:17; Ex. 90 (Downs Reb.) ¶168; Ex. 98 (Tanna 9/26 Tr.) 143:12-145:8.) Such perfusion flow testing with dyes was known at the time of the invention. (Ex. 93 (Downs 9/28 Tr.) 12:15-

24, 113:12-114:2; Ex. 102 (Downs 9/28 Tr. Ex. 5).)

12. A POSA, applying his/her knowledge and experience with intraocular implants and well-understood principles of fluid mechanics, would have been able to determine with reasonable certainty whether the length of a support, in conjunction with other features of the support, resulted in a device that would or would not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels. (*See, e.g.*, Ex. 90 (Downs Reb.) ¶¶168-171, 173; Ex. 93 (Downs 9/28 Tr.) 84:10-85:3, 98:10-99:2.)

13. Defendants demonstrated that they were able to understand with reasonable certainty that the accused Hydrus device permitted and did not substantially block fluid outflow from the trabecular meshwork when inserted into an eye, as evidenced by their repeated representations to the FDA and to doctors that they were training and certifying to use the device that the Hydrus provided this mechanism of action and facilitated fluid outflow from the trabecular meshwork into Schlemm's canal. (*See* Ex. 21 (IVANTIS_SS_00415663) at 415712 (the Hydrus's "[w]indows along the length of the implant allow natural trabecular flow through the body of [the] device"), 415721; Ex. 9 (Kimball Tr.) 94:21-23; Ex. 22 (IVANTIS_SS_00006997) at 7001; Ex. 23 (IVANTIS_SS_00276222) at 276226; Ex. 97 (Downs Op.) ¶¶87-89, 91, 95-96; Ex. 100 (Downs Reply) ¶¶45-49, 51-52, 62.)

14. Defendants themselves contend that a POSA would recognize that structures designed to minimize a support's contact with the walls of Schlemm's canal act to facilitate and not significantly block flow. (*E.g.*, Ex. 87 ('443 IPR Pet.) 30, 39-41, 50; Ex. 88 ('443 IPR Reynard Decl.) ¶¶69-71, 92-93; Ex. 89 (Tanna Op.) ¶¶141, 150, 153-154, 157, 239, 443.) Defendants contend that no testing was required to determine that such devices do not block flow. (*See id.*)

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CERTIFICATE OF SERVICE

I, Melanie K. Sharp, Esquire, hereby certify that on November 2, 2023, I caused to be electronically filed a true and correct copy of Concise Statement of Additional Facts in Support of Sight Sciences, Inc.'s Opposition to Defendants' Motion for Summary Judgment No. 3 of Invalidity for Indefiniteness with the Clerk of the Court using CM/ECF, which will send notification to the following counsel of record:

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I further certify that on November 2, 2023, I caused a copy of the foregoing document to be served on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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